March 5, 2004

THE COSMETICATOMETRY, AND FRAGRANCE ASSOCIATION

Docket Management Branch (HFA-305) Food & Drug Administration Room 1061 5630 Fishers Lane Rockville, MD 20852

E. EDWARD KAVANAUGH PRESIDENT

Re:

"CTFA International Cosmetic Ingredient Dictionary" [Citizen petition October 25, 1991], and, "Petition: International Cosmetic Ingredient Dictionary - Harmonization of Ingredient Labeling Names and Recognition of the Sixth Edition (1995)." [Citizen petition September 20, 1996 Withdrawal of Citizen Petitions

## Dear Sir or Madam:

The Cosmetic, Toiletry, and Fragrance Association (CTFA)<sup>1</sup>, pursuant to 21C.F.R. § 10.30 (g), respectfully requests that the Food and Drug Administration withdraw from consideration its citizen petitions filed on October 25, 1991, and on September 20, 1996. These petitions have not been ruled upon, nor have any public hearings been held to consider them.

The October 25, 1991 petition sought recognition of the adopted names in the Fourth Edition of the CTFA International Cosmetic Ingredient Dictionary (1991)(Fourth Edition Dictionary). As the adopted names in the Fourth Edition Dictionary have been superceded by later editions, the October 25, 1991 petition is therefore obsolete, and CTFA requests that it be withdrawn.

The September 20, 1996 petition sought recognition of the International Nomenclature Cosmetic Ingredient (INCI) names that were listed in the Sixth Edition of CTFA's International Cosmetic Ingredient Dictionary (1995) (Sixth Edition Dictionary). As the INCI names in the Sixth Edition Dictionary have been superceded by later editions, the September 20, 1996 petition is obsolete in that regard.

Additionally, action requested included: allowance of dual declaration of U.S. and EU approved colorants by INCI name and colour index number; use of the symbol "+/-" parenthetically with



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<sup>&</sup>lt;sup>1</sup>CTFA is the U.S. national trade association representing the personal care products industry. CTFA is comprised of over 300 active members that produce the vast majority of the cosmetics distributed in the U.S. and that also produce many over-the-counter drugs designed for dermal application. The association also has over 300 associate members that provide raw ingredients and suppliers and services to the industry. Many of CTFA's members are international companies that do business in foreign countries as well.

the term "may contain" for ingredient declaration for an interim period, followed by allowance of the symbol +/- alone; recognition of the name "Alcohol Denat" to represent all denatured alcohols then recognized for ingredient labeling; an orderly transition for labeling botanical ingredients by their Latin names with plant part and type of preparation; and finally, dual ingredient names for those European Union ingredients designated by "trivial" names. As many of the proposals for dual labeling, transition, and education have been in place for several years, the requests in this petition are no longer applicable and will need to be updated in a new petition. Therefore, for the reasons stated above, CTFA asks that this petition be withdrawn.

Sincerely,

Gerald N. McEwen, Jr., Ph.D., J.D.

Vice President - Science

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